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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/590,248  | 04/26/2007  | Simon W. Bayloff     | JJM5033USPCT        | 6950             |
| 27777   | 7590        | 01/15/2008           | EXAMINER            |                  |
| PHILIP S. JOHNSON<br>JOHNSON & JOHNSON<br>ONE JOHNSON & JOHNSON PLAZA<br>NEW BRUNSWICK, NJ 08933-7003 |             |                      | NGUYEN, BAO THUY L  |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1641                |                  |
|   |             |                      | MAIL DATE           | DELIVERY MODE    |
|   |             |                      | 01/15/2008          | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                       |                                       |  |
|------------------------------|---------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/590,248  | <b>Applicant(s)</b><br>BAYLOFF ET AL. |  |
|                              | <b>Examiner</b><br>Bao-Thuy L. Nguyen | <b>Art Unit</b><br>1641               |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. The preliminary amendment submitted 21 August 2006 has been received. Claims 1-15 are pending.

#### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3-5, 7-8 and 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Berke et al (US 5,084,245).

Berke discloses a device comprising a base component (i.e. cup-shaped body) on which a sample sensitive element is mounted and a guide member that is normally mounted on the base component in covering relationship to the reactive element.

With regard to claims 3 and 4, the base component and the guide member include means which holds the base component and the guide member together. The holding means may comprise a well in the base component and a complementarily shaped projection on the guide member. The projection is normally received in the well and held in place there by frictional engagement and/or snap-fit mechanical engagement. See column 2, line 59 through column 3, line 3.

With regard to claim 5, Berke teaches a vent for venting air from the well in the base component. See column 7, lines 15-21.

With regard to claims 7 and 8, Berke teaches at least one diagnostic test reagent provided on porous capture elements 42 and 44. See column 8, lines 18-38.

With regard to claim 11, Berke teaches a prefilter mounted on the distal end of the guide member and is in close capillary contact with the sample sensitive element of the cap. When the cap and the guide member are assembled, the prefilter is seen to be part of the cap. See column 9, lines 14-39.

With regard to claim 12, Berke discloses a flow director, 40, which may be transparent to indicate when the diagnostic test reagent has been wetted by an analyte solution by enabling a viewing of a change in color in membranes 42 and 44. See column 14, lines 28-38.

With regard to claim 13, Berke teaches an enzyme assay. See column 8, lines 17-26.

With regard to claim 14, Berke teaches antibodies as binding partners. See column 9, lines 52-66.

With regard to claim 15, Berke teaches the detection of multiple analytes. See column 9, lines 52-66.

*Claim Rejections - 35 USC § 103*

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 6, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berke et al in view of Sayles (US 5,429,804).

See the discussion of Berke above. Berke differs from the instant claim in failing to teach that the cap is at least partially transparent.

Sayles discloses a test device having a lower cup for receiving a fluid specimen and a lid containing a chamber having one or more reagent strips protruding therefrom. The lid is attachable to the cup and results can be read through a transparent area of the lid. See abstract. Sayles also teaches that on the rim, around the transparent area, can be written a plurality of indicia to indicate the particular test being done in the chamber segment below. See column 2, lines 46-50.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the base component of Berke such that it has at least a transparent area because such material is well known in the art. A skilled artisan would have had a reasonable expectation of success in including a transparent area in the device of Berke because Berke teaches that his device may be made from a variety of

material including plastic or glass, etc (see Berke, column 7, lines 37-44). It also would have been obvious to include different indicia corresponding to different regions of assays on the cap such as taught by Sayles because both Sayles and Berke teaches the possible detection of multiple analytes and indicia would be required to identify them.

6. Claims 2 and 9 are rejected under 35 U.S.C. 103(a) as obvious over Berke.

See the discussion of Berke above. Even though Berke does not specifically discloses the dimensions of the cap nor does Berke recites the uncompressed volume of the absorbent material, these limitations are nothing more than routine optimization in the art. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation."

Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art."

Application of Boesch, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980). Since Applicant has not disclosed that the specific limitations recited in instant claims are for any particular purpose or solve any stated problem and the prior art teaches that a variety of different commercially available absorbent may be use and that the specific selection often vary according to the samples being analyzed, absent unexpected

results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures known in the art.

### *Conclusion*

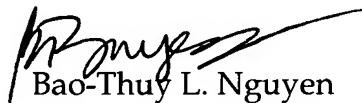
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday -- Thursday from 9:00 a.m. - 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Bao-Thuy L. Nguyen  
Primary Examiner  
Art Unit 1641  
12/31/07